

DOCKET NO.: CHIR-0212

PATENT

E3  
Cont

resuspended precipitate to hydrophobic interaction chromatography.

E4

Claim 17 (Twice Amended) A diagnostic kit comprising a protein having a molecular weight of about 24 kd, which specifically binds to the E2 protein of hepatitis C virus, or a functionally equivalent variant or fragment thereof.

#### Remarks

Claims 2-4, 7-10, 13-14, and 17 were pending. All pending claims were rejected in the Office Action. Claims 3, 4, 10, and 17 are amended herein. Claims 13 and 14 have been canceled without prejudice to be pursued in a continuation application(s). The Applicant respectfully requests that the Examiner reconsider and withdraw the rejections in view of the foregoing amendments and arguments that follow.

Preliminarily, Applicant gratefully acknowledges the withdrawal of the previous grounds of rejections and objection.

#### Rejections under 35 U.S.C. § 112, First Paragraph

Claims 13 and 14 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly non-enabled for encompassing *in vivo* therapy. Claims 13 and 14 have been canceled herein to be pursued in another application. This rejection has been rendered moot.

#### Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 2-4, 7-10, 13-14, and 17 were rejected under 35 U.S.C. § 112, second paragraph.

Claim 3 was rejected in view of the recitation ". . . protein, or functionally equivalent variant or fragment thereof, is a transmembrane protein." The Examiner questioned how the variants and fragments could themselves be considered transmembrane proteins. Claim 3 has been amended consistent with the Examiner's suggestion. This rejection has been obviated by amendment.

Claims 4, 10, 13, 14, and 17 were rejected as allegedly indefinite in view of the recitation "capable of specifically binding" to E2. Claims 13 and 14 have been canceled. Applicant has amended claims 4, 10, and 17 consistent with the Examiner's suggestions. Support for this amendment can be found in the claims and throughout the application as filed. This rejection has been obviated by amendment.

Claim 10 was rejected as allegedly indefinite in view of the recitation of "resuspending."

The Examiner maintains that this term denotes suspending in the original rough cellular precipitate. Applicant disagrees with this interpretation of resuspending. Applicant directs the Examiner to page 31, lines 23-28, of the application as filed, where it is clearly stated that the precipitate obtained was "resuspended" in PBS. Nonetheless, to advance prosecution, Applicant has amended claim 10 to recite that the precipitate was resuspended in buffer. Applicant requests that this rejection be withdrawn.

Claims 13, 14, and 17 were rejected as allegedly indefinite in view of the syntax. The Examiner alleged that it is unclear whether the protein, the variant, or both bind to E2.

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Claims 13 and 14 have been canceled. Claim 17 has been amended consistent with the Examiner's suggestion. This rejection has been obviated by amendment.

For the foregoing reasons, Applicant requests that claims 2-4, 7-10, and 17 be allowed at this time. A notice of allowance is earnestly solicited. If the Examiner thinks a telephonic discussion would be helpful, she is asked to contact the undersigned at 215-564-8352. Attached hereto is a marked-up version of the changes made to the claims by the current Response and Amendment. The attached page is captioned "Version with Markings to Show Changes Made."

Respectfully submitted,



Doreen Yatko Trujillo x 8352  
Registration No. 35,719

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WOODCOCK WASHBURN KURTZ  
MACKIEWICZ & NORRIS LLP  
One Liberty Place - 46<sup>th</sup> Floor  
Philadelphia, PA 19103  
(215) 568-3100 - Telephone  
(215) 568-3439 - Facsimile

VERSION WITH MARKINGS TO SHOW CHANGES MADE

**In the claims:**

Claim 13 has been canceled.

Claim 14 has been canceled.

Claims 3 has been amended as follows:

Claim 3 (Twice Amended) The process of claim 4, wherein the protein[, or a functionally equivalent variant or fragment thereof,] is a transmembrane protein.

Claims 4 has been amended as follows:

Claim 4 (Amended Three Times). A process for the preparation of a protein having a molecular weight of about 24kd [and capable of specifically binding to] which specifically binds to the E2 protein of hepatitis C virus, or for the preparation of a functionally equivalent variant or fragment thereof, comprising the steps of:

- i) contacting cells with a preparation of E2;
- ii) obtaining a membrane preparation from cells exhibiting binding to E2; and
- iii) purifying said protein from said preparation.

Claims 10 has been amended as follows:

Claim 10 (Amended Three Times) A process for the preparation of a protein having a molecular weight of about 24kd and [capable of specifically binding to] which specifically binds to the E2 protein of hepatitis C virus, or a functionally equivalent variant or fragment thereof, comprising the steps of:

- i) contacting cells with a preparation of E2;
- ii) obtaining a membrane preparation from mammalian cells selected for binding to E2;
- iii) precipitating the preparation with ammonium sulphate at less than 33 % saturation and retaining the supernatant;
- iv) precipitating the supernatant with ammonium sulphate at between 33 and 50 % saturation and retaining the precipitate; and
- v) resuspending the precipitate from step iv) in buffer and subjecting the resuspended precipitate to hydrophobic interaction chromatography.

Claims 17 has been amended as follows:

Claim 17 (Twice Amended) A diagnostic kit comprising a protein having a molecular weight of about 24 kd, [or a functionally equivalent variant or fragment thereof, and capable of specifically binding to] which specifically binds to the E2 protein of hepatitis C virus, or a functionally equivalent variant or fragment thereof.